

CLAIMS

We claim:

1. A crystalline rupatadine form-B characterized by having the melting point of about 110 - 115°C.
2. The crystalline rupatadine form-B as defined in claim 1, further characterized by a differential scanning calorimetric thermogram with endothermic peak at about 112°C.
3. The crystalline rupatadine form-B as defined in claim 1, further characterized by an x-ray powder diffraction spectrum having peaks expressed as 2θ at about 18.2, 18.5, 18.8, 19.5, 20.2, 22.7 and 23.8 degrees.
4. The crystalline rupatadine form-B as defined in claim 1, further characterized by an x-ray powder diffraction spectrum having peaks expressed as 2θ at about 9.4, 9.8, 14.9, 16.4, 18.2, 18.5, 18.8, 19.5, 20.2, 22.7, 23.8, 24.5 and 28.4 degrees.
5. The crystalline rupatadine form-B as defined in claim 1, further characterized by a Fourier transform Infrared (FTIR) spectrum as shown in figure 3.
6. A process for preparation of crystalline rupatadine form-B as defined in claim 1, which comprises suspending rupatadine in n-hexane, n-heptane, cyclohexane, diethyl ether or diisopropyl ether, stirring for at least about one hour and isolating rupatadine free base as crystalline form-B.
7. The process according to claim 6, wherein the stirring of the suspension is carried out for 1 to 10 hours at below the boiling temperature of the solvent used.
8. The process according to claim 7, wherein the stirring of the suspension is carried out for 3 - 6 hours at 15°C to the boiling temperature of the solvent used.
9. The process according to claim 8, wherein the stirring of the suspension is carried out for 3 - 6 hours at ambient temperature.
10. The process according to claim 6, wherein the isolation of the crystalline form-B is carried out by filtration or centrifugation.
11. A pharmaceutical composition comprising crystalline rupatadine form-B as defined in claim 1 and a pharmaceutically acceptable carrier or diluent.